

REMARKS

Claim 22 is currently pending in the application. Claims 1 through 21 have been canceled. Claim 22 has been amended. No new matter has been added by these amendments.

Applicants thank the Examiner for withdrawing several of the rejections from the previous office action.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 22 has been rejected on several grounds as allegedly indefinite.

The rejection of claim 22 for indefiniteness has been maintained on the ground that it is indefinite and confusing in the limitations “non-bound complexes” at lines 13, 15 and 16. The term “non-bound complexes” refers to any complexes not bound to the antibodies present in the at least one scrub zone. Applicants have amended claim 22 to better clarify this point.

Claim 22 has also been rejected as allegedly indefinite and inconsistent in the limitations “a subject” in line 2 and a “human subject of age 12 years or less” in lines 3 and 4. Applicants have amended claim 22 to resolve the inconsistency.

Claim 22 has further been rejected in the limitation “the complexes” because it is unclear from where this limitation derives antecedence. Applicants believe the amendments to claim 22 now make this clear.

Finally, claim 22 has been rejected as indefinite in the limitation “wherein color formation in the downstream capture zone resulting from the binding is indicative...” Applicants have amended claim 22 to clarify to what binding the color formation is due.

Reconsideration and withdrawal of the rejections is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph (New Matter)

Claim 22 has been rejected as allegedly containing subject matter which is not described in the specification.

Specifically, the Examiner alleges that the following limitations of claim 22 have descriptive support in the specification: “tagged antibody having been present in a dried state on the bibulous strip,” “complexes in the mixture,” “including the complexes if formed,” “at least one of the

complexes, if present,” “at least one scrub zone,” “non-bound complexes,” “the mixture comprising non-bound complexes, if present,” “any non-bound complexes, if present” and “antibodies specific for the complexes.” Support for each of these limitations is present in the specification as follows:

“tagged antibody having been present in a dried state on the bibulous strip”: Page 9, lines 2-4 state that “The strip [of bibulous material] has...a deposit of tagged purified antibody conjugate located immediately ahead of the sample receiving zone, which deposit is rendered flowable by contact with liquid sample.” A deposit of tagged antibody on a strip that is “rendered flowable by contact with liquid sample” must be in a “dried state” before the liquid sample mobilizes it; thus, support for the term “dried state,” which makes the claim easier to understand and shorter, is present in the specification. The subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement. MPEP § 2163.02.

“complexes in the mixture”: Page 9, lines 9-12 state that “[w]hen the test is run and the target bacterial antigen is present in the liquid sample, after the sample is applied to the strip and picks up the tagged antibodies as it flows along, conjugates of tagged antibody and target antigen form during further flow to the capture line...” Thus, the sample is a “mixture” of tagged antibodies and the liquid sample itself, in which “conjugates of tagged antibody and target antigen form”, i.e., “complexes” form in this mixture. Thus, support is present for this limitation. However, Applicants have amended claim 22 to recite “conjugates” rather than “complexes” to better reflect the terminology used in the specification.

“including the complexes if formed” and “at least one of the complexes, if present”: Please see argument above for “complexes in the mixture.”

“at least one scrub zone”: Support for the concept of having at least one scrub zone on the strip is literally present in the specification in Example 3, entitled “Reducing Conjugate and Capture Line Concentrations and Adding a Scrub Line” and Example 4, entitled “Reduced Concentrations of Capture Line and Conjugate with Multiple Scrub Lines.”

“non-bound complexes,” “the mixture comprising non-bound complexes, if present” and “any non-bound complexes, if present”: These terms have been removed from the claim by the amendments made in response to the 35 U.S.C. § 112 second paragraph rejections described above.

“antibodies specific for the complexes:” Page 9, lines 9-13 state that “[w]hen the test is run and the target bacterial antigen is present in the liquid sample, after the sample is applied to the strip and picks up the tagged antibodies as it flows along, conjugates of tagged antibody and target antigen form during further flow to the capture line, where tagged antibody-target antigen-fixed antibody ‘sandwiches’ form and become visible as a result of the massing of tag along the fixed capture line.” These antibodies, therefore, must be “specific” for the complexes or conjugates if they are able to bind them. The subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement. MPEP § 2163.02.

Reconsideration and withdrawal of the rejections are respectfully requested.

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

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